In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-0435V

Filed: November 29, 2012

(Not to be published)

MILDRED LAWRENCE,	*	
Petitioner,	*	Petitioners' Motion for a Ruling on the Record; Insufficient Proof of Causation; Vaccine Act Entitlement; Denial Without Hearing
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

DECISION[1]

On June 30, 2009, the petitioner, Mildred Lawrence, filed a petition for compensation under the National Vaccine Injury Compensation Program ("the Program"),[2] alleging that she suffered a rheumatological injury as a result of a hepatitis B ("hep B") vaccination that she received on July 18, 2006. Petitioner filed extensive medical records relating to her claim between December 17, 2009, and October 7, 2010.

On April 26, 2012, petitioner filed a "Motion for Decision on the Record." After careful consideration, however, I conclude that the information in the record does *not* show entitlement to an award under the Program.

[1]Because this document contains a reasoned explanation for my action in this case, I intend to post this order on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Therefore, as provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this entire document will be available to the public. *Id.*

[2] The statutory provisions governing the National Vaccine Injury Compensation Program are found in 42 U.S.C. § 300-10 *et seq*. (2006 ed.).

I. BACKGROUND

A. Facts

On July 18, 2006, petitioner was forty-seven years old. (Pet. Ex. 13 at 1.) On that date, petitioner received a hepatitis B vaccination from the Carroll County Health Department health center ("Health Department") in Carrollton, Georgia. (Pet. Ex. 5 at 2.) Prior to vaccination, petitioner had a history of hypertension, postpartum congestive heart failure, worsening general abdominal pain for at least nine months, muscle and joint aching, and pain in her right hip, ankles, and knees. (*See generally* Pet. Ex. 1.) Additionally, approximately two years prior to her receipt of the hepatitis B vaccine, petitioner sought treatment from rheumatologist Elena F. Flagg, M.D., who evaluated petitioner's complaints of worsening malaise, fatigue, and joint pain, as well as reports of an intermittent rash. (Pet. Ex. 2 at 1.)

Petitioner has stated that she "began to feel weak and dizzy," the evening after she received the hepatitis B vaccine. (Pet. Ex. 24. at 1.) Later that evening, petitioner presented at the Tanner Medical Center ("TMC") emergency room ("ER"), complaining of dizziness, as well as weakness and numbness in both legs, which she reported as having started thirty minutes before she came to the hospital. (Pet. Ex. 14 at 22.) Petitioner reported that she was currently taking four medications, including Rocephin, Zithromax, and Norvasc. (*Id.*) Dr. Thomas Fitzgerald's physical examination of petitioner was normal, except for a "very soft systolic ejection murmur." (*Id.*) Significantly, petitioner's blood pressure was 201/112, and Dr. Fitzgerald ordered lab work and an electrocardiogram ("EKG"). (*Id.* at 22-23.) Dr. Fitzgerald noted that the EKG showed occasional supraventricular beats, but otherwise revealed no acute changes. (*Id.* at 23.) Generally, Dr. Fitzgerald noted that petitioner's laboratory results were "completely normal." (*Id.*) Petitioner was advised to follow-up with her regular family physician, Dr. Haugabrook, if symptoms persisted. (*Id.* at 31.) She was seen by neurologist Reginald Hall, M.D., for an initial evaluation approximately two months later, on September 15, 2006. (Pet. Ex. 6 at 1-5.) After examining petitioner, Dr. Hall wrote, "not sure what to make of her symptoms given she had such a sudden onset after her Hep B shot * * * most likely need referral to rheumatology." (Pet. Ex. 6 at 4.)

Over the next eleven months, petitioner continued to report symptoms that she suspected to be vaccine-related, including dizziness, weakness and numbness in her lower extremities, nausea, headaches, heart palpitations, visual disturbances, muscle and joint aches, and a rash. (Pet. Ex. 3 at 2-6; Pet. Ex. 7 at 13-15, 56.) Petitioner consulted with different doctors, including a neurologist, a dermatologist (Pet. Ex. 7 at 13), a cardiologist (Pet. Ex. 7 at 1), and a rheumatologist (Pet. Ex. 11 at 2-6). She also sought treatment from an internist at the Immune Recovery Foundation. (*See* Pet. Ex. 8.) Petitioner's blood pressure was consistently noted to be elevated, which was thought to be causing some of her symptoms. (*See, e.g.*, Pet. Ex. 3 at 2-6; Pet Ex. 7 at 14.) Of these treating physicians, only rheumatologist Lamar Cousins, M.D., discussed a possible connection between the vaccine and petitioner's condition. He noted that "whatever adverse response she experienced to the Hepatitis B vaccine functioned only as a 'trigger' * * *. It is entirely possible that she just experienced the sudden onset of rheumatoid disease in conjunction of [sic] the vaccine." (Pet. Ex. 11 at 6.)

On September 9, 2006, petitioner submitted a VAERS report[3] describing the symptoms she attributed to the hep B vaccination. (Pet. Ex. 31 at 1.) She noted the onset of her symptoms as July 18, 2006, in the "PM." (*Id.*) She reported receiving the vaccine in the "AM" of that same date. (*Id.*) She also reported that she had been taking Zithromax and Recephin at the time. (*Id.*)

On May 31, 2007, Ms. Lawrence presented to Dr. Lamar Cousins with complaints of musculoskeletal discomfort. (Pet. Ex. 11 at 3.) Upon examination, Dr. Cousins diagnosed Ms. Lawrence with rheumatoid disease. (*Id.* at 6.) Dr. Cousins prescribed 10 milligrams of Prednisone to be taken in the morning, and scheduled a follow-up appointment in two weeks. (*Id.*) On June 14, 2007, Ms. Lawrence presented to Dr. Cousins for a follow-up visit, with recurring complaints of musculoskeletal discomfort. (*Id.* at 1.) Dr. Cousins suggested increasing Ms. Lawrence's Prednisone dosage to 10 milligrams in the morning and 5 milligrams in the evening, and recommended a follow-up in 10-14 days. (*Id.* at 1.) Dr. Cousin's impression was again noted as rheumatoid disease. (*Id.* at 2.)

On May 15, 2008, petitioner had a rheumatology evaluation with Dr. Robin Geletka, who noted that petitioner had been diagnosed with rheumatoid arthritis in 2007, and now presented with recurring complaints of joint pain and swelling. (Pet. Ex. 15 at 19.) Dr. Geletka's impression was rheumatoid arthritis, and Ms. Lawrence was instructed to start on 30 milligrams of Prednisone and taper to 10 milligrams over six days, with a follow-up appointment in two to three weeks. (Pet. Ex. 15 at 21.) On June 25, 2008, Ms. Lawrence returned for a follow-up appointment with Dr. Geletka and presented with a multitude of complaints, including pain in her back, fingers, and all joints; however, Dr. Geletka indicated that he did not observe any significant joint swelling. (Pet. Ex. 15 at 8-9.) Dr. Geletka's assessments were "patient with probable rheumatoid arthritis" and "pain syndrome likely due to a combination of a chronic back pain and fibromyalgia." (Pet. Ex. 15 at 9.)

On April 8, 2009, Ms. Lawrence presented to Dr. Geletka with swelling in her hands, stiffness, and anterior chest discomfort. (Pet. Ex. 15 at 1.) Dr. Geletka's impression again was probable rheumatoid arthritis and fibromyalgia. (Pet. Ex. 15 at 1.)

B. Procedural History

On June 30, 2009, petitioner filed the instant petition for compensation in the National Vaccine Injury Compensation Program. She alleged that she "suffered a rheumatologic injury" as a result of receiving a hepatitis B vaccination administered on July 18, 2006. (Pet. at 1-2.) The petition was assigned to Special Master Sandra Lord.

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[3] A VAERS report (*i.e.*, the Vaccine Adverse Event Reporting System) is to be filed when a patient suffers an adverse event soon after a vaccination. VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine. *See Howard v. Sec'y of Dep't of Health & Human Servs.*, No. 03-550V, 2006 WL 932381, at *9 (Fed. Cl. Spec. Mstr. Mar. 22, 2006); *see also Stapleford v. Sec'y of Dep't of Health & Human Servs.*, No. 03-234V, 2009 WL 1456441, at *15 (Fed. Cl. Spec. Mstr. May 1, 2009). *See generally* http://vaers.hhs.gov.

On March 17, 2010, in accordance with Special Master Lord's order dated February 12, 2010, petitioner filed an Amended Petition and her affidavit. The Amended Petition included significantly more factual detail, but did not otherwise alter the first Petition's basic allegation that petitioner "suffered rheumatologic injuries" as a result of a July 18, 2006, hepatitis B vaccination. (Am. Pet. at *Introduction*.)

Pursuant to the special master's Order dated March 19, 2010, respondent filed a "Rule 4(c) Report" on June 15, 2010, denying that compensation was appropriate in this case. Respondent argued there was no evidence in the medical records to support any causal relationship between petitioner's hepatitis B vaccination and petitioner's condition. Respondent's Report also stated that petitioner did not establish that the onset of her injury occurred in a medically appropriate time frame following her vaccination. (Resp't's Rule 4(c) R. at 26.)

On June 25, 2010, Special Master Lord ordered the petitioner to file a medical expert report no later than August 24, 2010. (Order, ECF No. 33.) Petitioner thereafter retained an expert to review her case, but the expert communicated that he would require additional time to review the pertinent medical information and draft his opinion, and petitioner therefore requested an extension of time until October 8, 2010. (ECF No. 35.) Special Master Lord granted this motion on August 24, 2010. (Order, Aug. 24, 2010.) On October 6, 2010, petitioner filed another motion for an extension of time to file an expert opinion, until November 22, 2010. (ECF No. 36.) The special master granted this motion on October 6, 2010. (Order, Oct. 6, 2011.)

From November 23, 2010, through January 21, 2011, petitioner filed three additional motions for extension of time. (ECF No. 39, 40, and 41.)

Petitioner finally filed an expert report, authored by Dr. Paul J. Utz, M.D., on February 17, 2011. (Pet. Ex. 37.) Dr. Utz concluded that "the immunological data and history in this case very strongly support the likely possibility that Petitioner, Ms. Lawrence, was in the process of developing RA at the time of her vaccination.* * * I further conclude that it is *plausible* that the Petitioner's immunization with a hepatitis vaccine *may* have contributed to activation of her immune system, and future development of synovitis and rheumatoid arthritis." (Pet. Ex. 37 at 3-4, emphasis added.)

On March 7, 2011, a status conference with the parties was convened, during which respondent requested that petitioner be ordered to file a supplemental expert report. (Order, ECF No. 43.)

On March 8, 2011, Special Master Lord ordered that by April 22, 2011, petitioner should file a supplemental expert report from Dr. Utz, in order to address the causation factors set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). (Order, ECF No. 44.) Petitioner thereafter requested and obtained several extensions of time in which to file a supplemental report, but eventually did not file any supplemental report.

On November 1, 2011, petitioner moved to substitute Richard Gage for Ronald C. Homer as her counsel of record in the above-entitled matter. (ECF No. 59.)

On April 12, 2012, respondent filed a motion for summary judgment, arguing that, viewing the facts in the light most favorable to petitioner, petitioner could not meet her burden of

proving that her vaccination of July 18, 2009, caused her "rheumatologic injury." (ECF No. 61.) On April 26, 2012, petitioner filed a motion seeking a decision on the written record. (ECF No. 62.)

On September 10, 2012, pursuant to Vaccine Rule 3(d), the case was reassigned to myself. (Order, ECF No. 63.)

II. DISCUSSION

To receive compensation under the Program, the petitioner must prove either: 1) that she suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table--corresponding to her vaccination, or 2) that she suffered an injury that was *actually caused* by a vaccine. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). In my examination of the filed medical records, however, I did not find in the record any evidence that Ms. Lawrence suffered a "Table Injury." Further, while a medical expert's opinion has been filed in this case, that opinion, of Dr. Utz, does *not* indicate that Ms. Lawrence's condition was *more probably than not* caused by her hepatitis B vaccine. Instead, Dr. Connor's report merely states that it is "plausible" that there exists a causal connection between Ms. Lawrence's vaccination and her rheumatoid arthritis. (Pet. Ex. 37 at 3-4.) The expert report also noted that petitioner's immunization "may" have contributed to her rheumatoid arthritis (*id.*), which again does not meet the burden of proving causation under the Program.

Under the statute, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not seem to support the petitioner's claim, a medical opinion must be offered in support that states that it is at least "more probable than not" that petitioner's injury was caused by the vaccination in question. Though petitioner has offered the expert report of Dr. Paul Utz, the report stated merely that it is "plausible" that petitioner's vaccination caused her rheumatoid arthritis. Further, Dr. Utz stated that "petitioner's immunization with a hepatitis vaccine *may* have contributed to * * * rheumatoid arthritis." (Pet. Ex. 37 at 3-4, emphasis added), which again does not meet the burden of proving causation to the level of "more probable than not," as required under the Program. Therefore, petitioner has not submitted a medical opinion that even *alleges* that it is more probable than not that petitioner's injury was caused by her vaccination.

In a motion filed April 26, 2012, petitioners requested that I rule upon the record as it now stands. Accordingly, I now do so.

I am, of course, sympathetic to the fact that petitioner suffers from a very unfortunate medical condition. However, under the law I can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or competent medical opinion to be, more probably than not, vaccine-caused. No such proof exists in the record before me. Accordingly, it is clear from the record in this case that petitioner has not demonstrated either that she suffered a "Table Injury" or that her condition was "actually caused" by a vaccination. Therefore, I have no choice but to hereby DENY this

claim. In the absence of a timely-filed motion for review of this Decision, the Clerk shall enter judgment in accord with this Decision.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master